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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,239	01/03/2006	Adam Alexander Tebbutt	1171/43247/160-PCT-US	3586

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CHICAGO, IL 60603

EXAMINER

OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
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3771

NOTIFICATION DATE	DELIVERY MODE
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12/28/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptodocket@trexlaw.com

Office Action Summary	Application No. 10/538,239	Applicant(s) TEBBUTT ET AL.	
	Examiner CLINTON OSTRUP	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/29/09 & 6/19/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 68-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 68-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 19, 2009 has been entered.

As directed by the amendment, claims 68, 85, 88, 89 and 90 have been amended and claims 1-67 are cancelled. Thus, claims 68-90 are pending in this application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 68-69, 77, 81 & 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Feinberg (1,445,010).

Regarding claim 68, Feinberg discloses a mouthpiece (figure 3) for the delivery of gases (air) from a source (13) to a user (human), comprising: an elbow connector (11) capable of receiving gases from the source (13) ; an outer flap (10) adapted to conform to the user's mouth (as shown in figure 1) and in fluid connection (air travels through 11 to 22 and 18 which are in fluid communication with 10) with said elbow

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connector (11), said outer flap (10) providing a substantial seal about the outside of the user's mouth (see figure 1) and capable of delivering said gases (air) from said elbow connector (11) to the user's oral passage (via 18); and nasal cannula (24) sealing in each of the nares of the user, said nasal cannula (24) attached to (via 25) and in fluid connection (air enters 25 to 24) with one of said outer flap (10) and said elbow connector (11) such that said nasal cannula is capable of delivering gases (air) to the user's nares. See: page 1, col. 1, line 55 - page 1, col. 2, line 97; page 2, col. 1, lines 6-24; and figures 1 & 3.

Regarding claim 69, Feinberg discloses an elbow connector (11) that is substantially L-shaped, where one end (part of 11 connecting 24 & 18) of the L-shaped elbow connector (11) is connected in use to said nasal cannula (24) and said outer flap (10), while the other end (part of 11 connected to 1) of the L-shaped nasal connector is adapted to receive said gases for delivery to the user. See: figures 1 & 3.

Regarding claim 77, Feinberg discloses a mouthpiece (figure 3) with the nasal cannula that comprises a pair (24) of nasal prongs.

Regarding claim 81, Feinberg discloses a mouthpiece (figure 3) with an outer flap (10) that includes a tubular passageway (for connecting 11 to 12) extending through said outer flap (10), said tubular passageway in fluid communication with said elbow connector (11) to deliver gases from said elbow connector (11) to the user's mouth. See: page 1, col. 1, line 55 - col. 2, line 64 and figures 1 & 3.

Regarding claim 84, Feinberg discloses a mouthpiece (figure 3) further including a vestibular shield (15) connected to said tubular passageway (for connecting 11 to 12),

said vestibular shield (15) being disposed in use within a user's mouth vestibule. See: page 1, col. 2, lines 75-80.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 70, 79, 80, 82-83 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feinberg (1,445,010), as applied to claim 68 above, and further in view of Robertson et al (EP 1075848 A2).

Feinberg discloses all the limitations of claims 70 and 88, except the elbow connector includes a swivelable joint to allow the elbow connector to swivel relative to the nasal cannula and outer flap.

Robertson discloses a mouthpiece with an elbow connector that includes a swivelable joint ([0025] of Robertson) that would allow the elbow connector (11 of Feinberg) to swivel relative to the nasal cannula (24 of Feinberg) and said outer flap (10 of Feinberg).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the elbow connector disclosed by Feinberg to have a swivel connection, as taught by Robertson in order to obtain an air delivery device that could be easily manipulated for attaching and detaching headgear.

Regarding claims 79 & 83, Robertson discloses forming a mouthpiece made of silicone [0026] and it would have been obvious to one having ordinary skill in the art to have formed the entire airway device taught by the combined references of the same material because it has been held that the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Regarding claim 80, Robertson discloses an outer flap (300) that has a lip (306) [0030] or (61) [0020]) extending around its perimeter to assist in sealing of said outer flap against the user's face and it would have been obvious to one having ordinary skill in the art to have modified the flap (10 of Feinberg) to have an outer lip as taught by Robertson in order to provide a user with a good seal.

Regarding claim 82, Robertson discloses a tubular passageway (304) that contains two outlets (302 & 303) to direct gases flow around the sides of the user's mouth as gases flow out of said tubular passageway and into the user's mouth and it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the gas passageway disclosed by Feinberg, by using a secondary passageway, as taught by Robertson in order to ensure proper delivery of air to a user even in the event that of occlusion of one outlet.

6. Claims 71 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feinberg (1,445,010) in view of Robertson et al (EP 1075848 A2), as applied to claims 68 and 70 above, and further in view of Daniell et al., (EP 0845277 A2).

The combined references disclose all the limitations of claims 71 and 89 except the elbow connector having an outlet vent to allow diffusion of the user's exhaled gas.

Daniell teaches a swivel type elbow connection with an outlet vent (37 of figure 8) that allows a patient to exhale through the nasal passage or through the mouth. See: col. 8, lines 22-45.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the swivel elbow connector disclosed by Robertson with the swivel elbow connector with an outlet, as taught by Daniell in order to obtain a gas delivery apparatus that would allow a patient to exhale either through the nasal passageway and/or the mouth based upon the patient's individual breathing habits or desires.

7. Claims 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feinberg (1,445,010) in view of Robertson et al (EP 1075848 A2) in view of Daniell et al., (EP 0845277 A2), as applied to claims 68, 69, 70 and 71 above, and further in view of Ging et al., (2003/0196662).

The combined references disclose all the limitations of claim 72 except an elbow connector comprises a plurality of apertures in the apex of the L-shape of the elbow connector with the apertures adapted to vent gases exhaled from the user.

Ging teaches an elbow connection (360) assembly with a vent cover (figures 20-22d) that have a plurality of apertures (390) in the apex of an L-shape of the elbow connector and the apertures adapted to vent gases exhaled from the user. See: figures 20-22d and [0166].

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plurality of outlet apertures, as taught by Ging, instead of a single outlet aperture, as disclosed by Daniell in order to form a gas delivery device that allows a patient to exhale either through the nasal passageway and/or the mouth based upon the patient's individual breathing habits or desires that would continue to function even if one of the apertures becomes blocked or closed.

Regarding claim 73, Ging teaches an elbow connector (360) that has an outlet vent comprised of a plurality of apertures in the shape of ovals (figure 21) squares (figure 22) and circles (figure 22d) which would allow diffusion of the user's exhaled gases and it would have been obvious to one having ordinary skill in the art to have formed elongate and tapered apertures so as to be larger proximal to said swivelable joint and narrower distal to said joint, as it has been held that a change in the shape of a prior art device is a design consideration within the skill of the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Regarding claim 74, Ging teaches an elbow connector that has a ledge (figures 20-22d) formed by a reduction in the diameter of said elbow connector and the reduction of the diameter of the elbow would be formed distal to said swivelable joint (45 of Robertson) with the plurality of apertures (390 of Ging) formed on the ledge to diffuse gases exhaled by the user. See: figures 20-22d of Ging and [0166].

8. Claims 75-76, 78, 85-87 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feinberg (1,445,010), as applied to claim 68 above, and further in view of Goldstein (6,012,455).

The combined references teach all the limitations of claims 75 and 85, except the extension mechanism adapted to allow the nasal cannula to adjustably extend from the elbow connector or outer flap.

Regarding claims 75 and 85 Goldstein teaches a nasal cannula that includes an extension mechanism (100 & 102 and col. 5, lines 38-43) that would allow the nasal cannula to adjustably extend from the elbow connector (11 of Feinberg) or said outer flap (10 of Feinberg).

It would have obvious to one having ordinary skill in the art at the time the invention was made to have modified the nasal cannula disclosed by Feinberg by utilizing nasal cannula members with an extension mechanism, as taught by Goldstein, in order to form a mouthpiece with nasal cannulas that can be easily adjusted to provide a comfortable fit to a user.

Regarding claim 76 and 86, Goldstein teaches the extension mechanism as a series of bellow-like corrugations (figure 14) on the nasal cannula that allows the length of said nasal cannula to be adjusted. See: col. 5, lines 38-43.

Regarding claim 78, 87 & 90, the nasal cannula taught by Goldstein is capable of detaching (via disconnecting tubes) from the elbow connector (11 of Feinberg) and/or the said outer flap (10 of Feinberg), which would allow for different sized nasal cannula to be connected to the said elbow connector (11 of Feinberg) and/or the outer flap (10 of Feinberg).

Response to Arguments

6. Applicant's arguments with respect to claims 68-90 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771